

Notice of Allowability

Application No.

09/980,277

Applicant(s)

RABELLO ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
ewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative
he Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to the Amendment of March 9, 2004 and the interview of May 26, 2004.

☒ The allowed claim(s) is/are 9-13.

☒ The drawings filed on 29 March 2002 are accepted by the Examiner.

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the
International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements
oted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF
INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of
Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of
each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the
attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date ____

☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date part of 0504.

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other ____.

EXAMINER'S AMENDMENT

1. This action is in response to the Amendment filed March 9, 2004, and to the interview concluding May 26, 2004. Claims 1-8 were canceled by the Amendment of March 9, 2004; accordingly, the rejections of those claims set forth in the Office action of September 9, 2003 are moot. The remaining objections set forth in the Office action of September 9, 2003 are withdrawn in view of the Amendment filed March 9, 2004 and further in view of the below examiner's amendment. Further, new claims 9-13 (added by the Amendment of March 9, 2004) are allowed, subject to the below examiner's amendment.

2. It is noted that the abstract filed March 9, 2004, as well as the paper and computer readable forms of the Sequence Listing filed March 9, 2004, have been entered.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with B.J. Sadoff on May 26, 2004.

4. In accordance with 37 C.F.R. 1.126, allowed claims 9-13 will be renumbered as claims 1-5, respectively (see MPEP 608.01(j)). It is noted that original claim numbers are employed in the below examiner's amendment.

5. **The application has been amended as follows:**

Amend the claims as follows:

9. A method for the detection of parasites of the Schistosoma genus in a biological sample ~~wherein a specific region of the DNA of the Schistosoma genus contains SEQ ID NO:1~~, said method comprising the steps of:
- (a) extracting Schistosoma sp. DNA from a biological sample;
 - (b) amplifying by PCR ~~[[of]]~~ a specific region of said Schistosoma sp. DNA obtained in step (a) with ~~oligonucleotide primers~~ a primer pair consisting of ~~the sequences of~~ SEQ ID NO:2 and SEQ ID NO:3, to obtain amplified products; and,
 - (c) separating the amplified products obtained in step (b) by electrophoresis to obtain separated products, and visualizing said separated products to detect the presence of any parasites of the Schistosoma genus in the biological sample.
10. The method according to claim 9, wherein in step (c) the amplified products of step (b) are separated by electrophoresis in polyacrylamide gel and visualized by colouring with silver salts.
11. An oligonucleotide A primer pair ~~selected from the group~~ consisting of SEQ ID NO:2 and SEQ ID NO:3.
12. A kit to detect the presence of an organism of the genus Schistosoma in a biological sample, said kit comprising ~~an oligonucleotide primer selected from the group~~ a primer pair consisting of SEQ ID NO:2 and SEQ ID NO:3.
13. The kit according to claim 12, further including a protocol and instruction manual ~~for the user~~.

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Amend the specification as follows:

On page 18, at line 23, after "GLASS-MAX[®]" delete "(system used to purify DNA fragments)".

Substance of Interview concluding May 26, 2004

6. The examiner contacted Applicant's representative by phone on May 24, 2004 to propose claim amendments that would limit claims 9-13 to the primer pair with which unexpected results (i.e., sensitive detection of multiple *Schistosoma* species) were exemplified in the specification. The examiner also proposed amending the specification to delete unneeded generic information regarding a trademark that constituted new matter. On May 26, 2004, Applicant's representative contacted the examiner and agreed to the proposed amendments. Claims 9-13 are therefore allowed, subject to an examiner's amendment.

Oath/Declaration

7. It is noted that the requirement for a new oath/declaration set forth in the prior Office action is waived, as it is clear that the instant application is a 371 of PCT/BR01/00035.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line that extends to the right.

Diana B. Johannsen
Primary Examiner
May 30, 2004